

REMARKS

As a supplement to Applicant's response filed October 31, 2007, the Examiner is respectfully requested to consider the following. On May 26, 2006, Applicant submitted a Declaration entitled "DECLARATION OF GARRET D. CAWTHON UNDER 37 C.F.R. §1.132," along with a response to an Office Action dated November 30, 2005. Applicant respectfully submits that the aforementioned Declaration provides evidence of secondary factors which support a finding of non-obviousness of the claims of the subject application. For example, the Declaration establishes, *inter alia*, that multiple embodiments of the claimed invention have been recognized by experts in the relevant field as being a significant advance over the prior art. In particular, the subject matter of the present application has been recognized by the medical community for its unique technology and performance, as evidenced by two significant awards that have been bestowed upon Applicant for the innovation represented by the present application. These two awards are discussed further below.

Products that embody the claimed invention achieved a first place finish at the 2005 Technology and Innovation Forum hosted by MedAssets. MedAssets is a margin and cash flow improvement company providing innovative solutions for healthcare providers and has over 22,000 hospitals, nursing homes and physician offices in its membership, making it the third largest Group Purchasing Organization in the U.S. The presenters at the 2005 Technology Forum were 47 high-tech healthcare companies who were preselected to present their new products. A panel of independent judges was selected from an array of hospitals, nursing homes and other institutions in order to provide an objective evaluation of the products presented by each of the 47 companies. The grading criteria (based on a 4.00 scale) used by the judges were as follows, and the present Applicant's scores for the inventive compositions are set forth in parentheses:

Vendor's technology...

- is new and can be considered "breakthrough" technology (4.00).
- will have a significant impact on improving patient care (3.93).
- will have a significant impact on improving labor efficiency (3.91).
- will have a significant impact on improving cost efficiency (3.84).
- will benefit the MedAssets' contract portfolio (3.81).

The overall score awarded to the present Applicant for the inventive compositions was 3.90, which was the highest out of all 47 companies. Of particular relevance is the fact that the inventive compositions were given a 4.00 of 4.00 score for the “breakthrough technology” category. Additionally, as a result of the success at the Technology Forum, Applicant was able to quickly establish a sales contract with the MedAssets organization. Attached hereto as Exhibit A is a copy of the letter reporting the results of the Technology Forum.

As also indicated in the aforementioned Declaration, spray-on products that embody the invention described and claimed in the present application were selected as a finalist for the Henry Vogt Award for Product Innovation. The judges selected for evaluation of products in the Vogt competition represented a collection of technical and business experts in the Louisville, KY area. In determining which product should receive the Award, each of the judges was requested to provide an objective evaluation of the products based on the following factors: innovative content, technical excellence, strategic business planning, potential for improving competitiveness, potential market value, capacity to generate employment by opening new markets or starting new enterprises, anticipated social or environmental benefits, willingness to locate all or part of operations in the greater Louisville area and demonstrated need or start-up status.

After the filing of the previous Declaration, Applicant learned that he had been awarded the Vogt Invention and Innovation Award and presented with a \$50,000 award for the products that embody the invention described and claimed in the present application. A copy of a newspaper article from the Louisville Courier Journal, a copy of which is attached hereto as Exhibit B, confirms this award and provides testimonials from members of the medical community about the advantages of the claimed compositions.

In view of the foregoing, Applicant respectfully requests that these objective indicia of non-obviousness be reconsidered and given proper weight as relevant to patentability of the subject application in line with the holding of Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).

Closing

In view of the foregoing remarks, together with the attached Exhibits and the response submitted October 31, 2007, it is respectfully submitted that the present application is in condition for allowance with pending claims 39-53, 57, 60, 74-76 and 87-94.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

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December 8, 2005

Garrett Cawthon
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Dear Garrett,

Thank you for participating in the 2005 Technology and Innovation Forum hosted by MedAssets Supply Chain Systems. This event was viewed as a great success by MedAssets and the Advisory Committee members of MedAssets Supply Chain Systems which attended.

Based on the feedback which MedAssets Supply Chain Systems received from its Advisory Committee, your company has been selected to advance to the next step in our contract review process. Please contact John Julian at (314) 291-2920 who is the designated contract manager for your product lines. In some cases, the committee has asked that additional evaluations be completed prior to sending a formal Request for Proposal (RFP).

Again, thank you for your participation, and we look forward to further discussions with your company.

Sincerely,

Joseph Dysko
Executive Director
Engineering and Capital Resource Group
Materials Management Division

cc: Mark Miriani, MedAssets Supply Chain Systems
Frank Gillespie, MedAssets Supply Chain Systems

Touchless Care Concepts, LLC Ranking

| Booth 34 Touchless Care Concepts, LLC | | |
|---------------------------------------|-----------------------------|---------|
| Question 1 | Breakthrough Technology | 4.00 |
| Question 2 | Improving Patient Care | 3.93 |
| Question 3 | Improving Labor Efficiency | 3.91 |
| Question 4 | Improving Cost Efficiency | 3.84 |
| Question 5 | Benefit MedAssets Portfolio | 3.81 |
| | Overall Score | 3.90 |
| Rank | | 1 of 47 |

Spray-on products offer healing touch

Inventor's ointments treat diaper rash, skin problems

By Bill Wolfe
bwolfe@courier-journal.com
 The Courier-Journal
 Monday, September 3, 2007

Some entrepreneurs may seem to have a magic touch. For inventor Garret Cawthon, an absence of touch is the magic.



Garret Cawthon displayed his Touchless Care Concepts products. He says they're quicker to apply, save money and are more comfortable for patients. Cawthon's business plan focuses on marketing to institutions, such as hospitals and nursing homes. (By Chris Hall, The Courier-Journal)

Cawthon's Touchless Care Concepts formulates and sells spray-on ointments for treating diaper rash and other skin problems. The products are being used or evaluated at hospitals and nursing homes across the nation -- including prominent institutions such as the Johns Hopkins Hospital and the Mayo Clinic.

Touchless Care Concepts took first place this year in an evaluation of new technology by MedAssets, a group-buying organization with about 30,000 institutional members, and also won a \$50,000 Vogt Invention and Innovation Fund award.

The appeal of the products? They are quicker and easier to apply, are more comfortable for patients and save money, said Cawthon, who came up with the idea as a class project at the University of Louisville while working on his business degree about eight years ago. The assignment involved creating a business plan for a new venture, and Cawthon found inspiration close at hand.

His daughter was about 2 then, and Cawthon was perplexed by how messy it was to apply the usual thick ointment.

He thought, "You know, I can invent a spray-on diaper-rash ointment that doesn't run off the skin," said Cawthon, who had earned a doctorate in chemical engineering and had patented several previous inventions.

Cawthon left the class with an "A" on the assignment -- and with the groundwork for a new company. He filed a patent application for his spray-on process in 1999 and was promoting the product at trade shows the next year.

The company currently offers three sprays -- one with zinc oxide, a clear version and one with an antifungal formula. Two more products will be announced in coming months, Cawthon said.

The Touchless Care products have earned praise from people like Karrie Walp, a registered nurse at Kosair Children's Hospital. She uses the ointments at home and thinks they would work well at the hospital.

Walp doesn't normally care for babies in her job, but recently took a shift in the newborn unit and saw how thick, sticky ointments could further irritate broken skin when cleaned off.

"We were using this cream that was sticking to their bottom, and when we'd go to wipe it off, it was making the wound worse," she said. With the Touchless Care products, "you spray it on and it's just got enough to keep it on."

The sprays also drew compliments from Mary Hatch, a registered nurse in upstate New York.

Rubbing thick ointments onto damaged skin can be painful and can cause additional damage, she said. With Cawthon's product, "you don't have to rub it in. Squirt, squirt, you're done."

Hospitals and nursing homes should find that the no-touch approach saves time and money and is better for patients, Cawthon said. "All you have to do is spray it on, and you can immediately ... rediaper the patients. There's no rubbing. There's no caregiver-to-patient contact. And so the application time is only about like 2 or 3 seconds versus a minute to a minute and a half" for rub-on ointments.

Applying a thin coating of ointment directly to the skin -- rather than squeezing a glob onto latex gloves and then rubbing that onto the patient -- also cuts waste and saves money, he said.

Cawthon's efforts to market the product were sidetracked early on by the birth of a son, Max, who had severe medical problems.

"Once I got him kind of healthier, I went back to the business about three years ago and have been pushing it ever since," he said.

Cawthon's business plan focuses on marketing to institutions. "We could be in the Wal-Mart shelves or the Walgreen shelves ... but it's easier for us, being small, if we just sell to a hospital and let them parcel it out to their patients," he said.

Perhaps surprisingly, there's a bigger market for diaper-rash medications for adults in nursing homes or other institutional care than there is for babies, he said.

There are about 8 million diaper-age babies in the United States at any time, and annual sales of rash products are about \$100 million, he said. The adult market is about \$500 million a year for 20 million to 25 million incontinent patients.

About half of incontinent adults are served by institutions, Cawthon said, "so if we get one wound-care decision-maker, one hospital, to select our product as the product of choice ... we get so many more sales than trying to go to individuals and do mass-marketing types of advertising."

Still, breaking into the market is a challenge, he said, because large drug companies have long-term contracts with the hospitals.

"It just really takes some arm-twisting almost to get people to switch, even though you're a better product for a cheaper price. That's our biggest hurdle."

Cawthon said he hopes to enlist a local hospital for clinical trials of his products to prove their effectiveness. But he plans to build sales slowly and has avoided any expansion that would require venture-capital partners.

"They'd probably be growing this fivefold or tenfold to what I'm doing right now," Cawthon said. His approach is "much more controlled. But that's how I am. I'm pretty conservative about things."

The inventor said he takes the same approach to business as he takes to marathon races and events such as last weekend's Ford Ironman Louisville triathlon -- a 2.4-mile swim, a 112-mile bicycle ride and a 26.2-mile run. Cawthon said his time was 13 hours, 2 minutes, compared with the winning men's time of 8 hours, 38 minutes.

"That's my conservative outlook. I don't overly go out there and kill myself," he said. But "I'm always successful. I always finish the race."

Reporter Bill Wolfe can be reached at (502) 582-4248.